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ABSTRACT

Since 1972, the issue of human rights protection has grown in complexity and intensity. Congress has passed four laws: Family Educational Rights and Privacy Act of 1974: Freedom of Information Act, as amended: Privacy Act of 1974: and National Research Act of 1974. From 1971-1980, the Department of Health, Education and Welfare (DHEW) and then the Department of Education and Department of Health and Human Services (DHHS) required that all prospective grantees of federal funds provide assurances to protect human subjects involved in research activities. Recent amendments to these regulations have exempted broad categories of research which normally present little or no risk of harm to subjects. Researchers have expressed concern over the conflict between the Freedom of Information Act (when the person who paid for a study through taxes believes he or she has a right to the data that was collected), and the Privacy Act and DHEW/HHS regulations (when the person who provides data does so only under the condition that confidentiality is maintained). Investigation of current operating procedures of the federal government reveals nine areas which constitute an informal system for protection of human subjects. (BW)

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FEDERAL ADMINISTRATIVE LAW –PRIVACY, FREEDOM OF INFORMATION AND PROTECTION OF HUMAN SUBJECTS– AFFECTING EDUCATIONAL RESEARCH

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Privacy and the protection of human subjects has become an important issue at both the federal, state and local levels. This paper provides a history of the attention the federal government has paid to the protection of an individual's basic rights, including the need to know as well as the right to privacy, and its impact on the educational research community.

Federal attention to protecting research subjects emerged in the 1960's primarily in response to issues involving health research. By 1965, the National Institute of Health had formulated a research-ethics policy for clinical research, broadened the next year to include other forms of health research and experimentation. At about the same time, Congress became concerned with privacy invasion in research in drug usage and in the accumulation of data in large scale surveys.

The Office of Education (OE) first came under scrutiny in 1968, when several Congressmen vehemently questioned a number of items in the Minnesota Multiphasic Personality Index, items they later described as "injuring private sensitivities." Soon OE was running checks on questionnaire items through both clearance officers and its own internal review committee.

Federal Legislative Efforts

Since 1972, the issue of human rights protection has grown in complexity and intensity. Congress has passed four laws and they have

been codified to differing degrees in regulations. These laws which affect the activities of educational research are:

(1) Family Educational Rights and Privacy Act of 1974 (FERPA),[1]

(2) Freedom of Information Act, as amended,[2]

(3) Privacy Act of 1974,[3]

(4) National Research Act of 1974.[4]

The Family Educational Rights and Privacy Act (FERPA) became law in 1974 based on an amendment to the Education Amendments offered on the Senate floor by the then New York Senator James Buckley without hearings or committee deliberation. Buckley's intent was two-fold: to assure parents of the right to see their children's school records and to prevent disclosure of these records to third parties. According to this legislation:

-- data may not be made available in personally identifiable manner from school records in most cases unless there is written consent of the parents,

-- personal information will only be transferred to a third party on the condition that such party does not share information with any other party without consent of the parents,

-- components of written consent by the parent or eligible student must be specified.

Educational researchers immediately saw a potential problem in FERPA--that is, schools would be prohibited from transferring data from educational records to third parties without first announcing the intention to do so, stating the purposes for which the data are being released, and obtaining the parents' or students' written consent for release.

However, the law does make exceptions to the written consent requirement. Two of them are significant to educational research and development institutions. These are:

(1) school personnel with "legitimate educational interests" may be exempt, and

(2) organizations conducting studies for, or on behalf of, local and state educational agencies or institutions for the purpose of developing, validating or administering student aid programs, and improving instruction may be exempt.

Research organizations and individuals doing research who qualify under this last exception must conduct their studies "in such a manner as will not permit the personal identification of students and their parents by other than representatives of such organization." The purposes of their studies must be made known to schools, and personal identifiers must be destroyed when "no longer needed for the purpose for which the study is conducted."

Since the law was passed, the Fair Information Practices Office, created in HEW and now the Division of Education Data Control in the Department of Education, has received over 5,000 inquiries and 400 complaints per year from parents and students. All but approximately 25 per year are administratively resolved.

The Freedom of Information Act (FOIA), as amended in 1974, provides for the release of information held by the federal government to the public to the greatest extent possible. Exemptions of documents are permitted in nine categories, two of which are important to educational

researchers: unwarranted invasion of privacy and confidential information of a commercial nature. FOIA places at the disposal of educational researchers a wealth of information about the techniques and procedures of a specific piece of research, making it possible to subject federally sponsored research to the kind of scrutiny which academicians normally give their peers' work.

The Privacy Act of 1974 is designed "to provide certain safeguards against an invasion of personal privacy by federal agencies . . ." by regulating the establishment and use of records on identifiable individuals, whether for administrative or research purpose. Under the Privacy Act of 1975, DHEW and now the Department of Education must identify and publish records systems, assure the confidentiality of privacy information in those systems, and allow access to those records by affected individuals. The Privacy Act subjects data collected for statistical purposes to the same provisions as data collected for administrative purposes. That requirement is unfortunate because educational studies are often voluntary and therefore, depend, in large measure, on the credence given to the data collectors' pledge of confidentiality. Strong confidentiality measures that protect individual privacy are a necessary and integral part of educational research. Furthermore, a Privacy of Protection Study Commission was established to study governmental, regional and private data banks and recommend information practices. In July, 1977, the seven member Commission, based on its two year study, submitted its recommendations to the President.[5]

In the area of research, the Privacy Commission recommended the release of "personally" identifiable data for authorized research purposes without parental consent. However, no research should be

conducted with children without parents' prior knowledge and approval. Furthermore, the Commission's suggestions aim at preventing information gathered for research or statistical purposes from being used for any other purpose in identifiable form without the consent of the subject. Congress has not acted upon the recommendations of this Commission.

The National Research Act authorized the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was responsible for:

1. developing guidelines for the protection of human subjects and the boundaries between research and routine practice,
2. risk/benefit criteria and assessment,
3. guidelines for selection of subjects, and
4. requirements for Informed Consent.

Public hearings were held by this Commission to discuss issues identified under the Act:

-- the use of children as subjects of research
-- whether children seven years of age or older are capable of understanding the procedures and general purpose of research and are able to indicate their wishes regarding participation,
-- the need for an Institutional Review Board to determine that the research is sound and significant.

To administer the Privacy Act, the Paperwork Reduction Act of 1980 created the Office of Information and Regulatory Affairs in the Office of Management and Budget.

Federal Regulatory Efforts

From 1971-1980, the Department of Health, Education and Welfare (HEW) and then the Department of Education required that all prospective grantees of federal funds provide assurances to protect human subjects involved in research activities. This responsibility was transferred to the Department of Health and Human Services (HHS) upon the creation of the Department of Education. In January 1981, the Department of Health and Human Services made major amendments to the policy.

Originally, guidelines for establishing procedures were published in a National Institute of Health/DHEW document entitled "The Institutional Guide to DHEW Policy and Protection of Human Subjects"[6] and its technical amendments, entitled "Protection of Human Subjects."[7] As part of these procedures, each research institution had to provide a statement of compliance assuring DHEW/HHS that it would establish and maintain a competent institutional review board to analyze activities and to determine that: (1) the risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks; (2) the rights and welfare of any such subjects will be adequately protected; (3) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provision of the regulations; and (4) the conduct of the activities will be reviewed at timely intervals.

According to DHEW guidelines, an individual is considered to be "at risk" if he or she may be exposed to injury--physical, psychological, social or other--as a consequence of participating as a subject in any research, development or related activity. Obvious examples of risk include requiring strenuous exertion or subjection to deceit, public

embarrassment or humiliation. Research which could not be condoned would be that leading to discomfort, anxiety, harrassment, invasion of privacy or any action that constitutes a threat to the subject's dignity through the imposition of demeaning or dehumanizing procedures. In educational research, specific examples include:

(1) Educational or economic risk. This occurs when a new curriculum is introduced and children fail to learn by its methods or materials. Also, wasting time may be considered an educational or economic risk.

(2) Over-Testing. Children may be tested too often or for an excessive period of time. Over-testing is often tied to the validation and standardization of instruments or to the evaluation of new instructional programs.

(3) Labeling. Labeling of children as needing special education or as representing minorities or low-income families clears the way for stereotyping and stigmatized behavior.

(4) Expecting or forcing continued participation. Withdrawing from a project, although legally required as an alternative, may produce guilt or fear on the part of the children.

(5) Inappropriate questions. Each time a question is asked, the subject is being asked to evaluate, to consider, to determine. When questions have a behavioral orientation, or when they ask about peer or family relationships, the subject is asked to provide sensitive information.

(6) Attitudes of researchers. The sometimes demeaning attitude of researchers reflects their commitment to generating knowledge rather than their concern for the effects of the research on the subjects.

(7) Misuse of findings. Omission and commission reflect two different kinds of misuse. Omission occurs when the lack of feedback on the research findings leaves the subject anxious about the outcome or unable to benefit from the findings. Commission occurs when findings are made available selectively to support prejudices or when findings are made available without respect for the privacy rights of the subjects.

Safeguarding the rights and welfare of subjects at risk in activities supported under grants and contracts from DHEW/HHS is primarily the responsibility of the institution which receives or is accountable for the funds. To this end, recipients or prospective recipients of support must provide written assurances that they will comply with DHEW/HHS policy. Each assurance must include a statement of compliance for initial and continuing institutional review board (IRB) review of the support activities; a set of implementing guidelines, including identification of IRB members and a description of its review procedures; or in the case of special assurances concerned with single activities or projects, a report of initial findings of the IRB and of its proposed continuing activities.

These basic procedures were amended in January, 1981[8] by the Department of Health and Human Services. Responding to the recommendations of the National Commission for the Protection of Human Subjects of

Biomedical and Behavioral Research and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research concerning institutional review boards, the amendments substantially reduced the scope of the existing regulatory coverage by exempting broad categories of research which normally present little or no risk of harm to subjects.

Specifically, the new regulations:

(1) exempt from coverage most social, economic and educational research in which the only involvement of human subjects will be in one or more of the following categories:
   (a) the use of survey and interview procedures;
   (b) the observation of public behavior; or
   (c) the study of data, documents, records and specimens.

(2) require IRB review and approval of research involving human subjects if it is supported by department funds and does not qualify for exemption from coverage by these regulations.

(3) require only expedited review for certain categories of proposed research involving no more than minimum risk and for minor changes in research already approved by an IRB.

(4) provides specific procedures for full IRB review and for expedited IRB review.

(5) designate basic elements of informed consent which are necessary as a prerequisite for humans to participate as subjects in research.

(6) indicate circumstances under which an IRB may approve withholding or altering some of the elements of the informed consent.

(7) establish IRB membership requirements.

These regulations are applicable only to research carried out by the Department of Health and Human Services, not research carried out by other federal agencies or by non-federal institutions. However, it can be expected that the Department of Education will issue regulations adopting much of the HHS regulations.

A case study of the application of the protection of human subjects in an educational research and development institution is documented in the appended review procedures used by Research for Better Schools, Inc., a regional educational laboratory in Philadelphia.

Conflict Among Legislation

Members of the research community have expressed concern over the conflict between the Privacy Act and DHEW/HHS regulations for the protection of human subjects (National Research Act) on one hand and the Freedom of Information Act on the other. The problem may be further stated as follows: guaranteeing confidentiality to research participants is mandatory if sound research is to be conducted; however, conflict between these acts arises from opposing values, that is, when the person who paid for a study through taxes believes he or she has a right to the data that was collected (the basis for the Freedom of Information Act), and the person who provides the data does so only under the condition that confidentiality is maintained (viewpoints presented by the Privacy Act and National Research Act).

The concern is that through the FOIA, personally identifiable data collected under the auspices of a federally funded project might have to be made available to members of the public upon their request. All data or documents in the possession of a federal agency (e.g., Office of Education or National Institute of Education) are accessible under FOIA; however, documents or data in the hands of contractors are not covered by FOIA. Therefore, these requests for information would have to go through the funding agency, e.g., NIE, and the concern was that project monitors could request and the R&D group would have to oblige with the data requested. This would force the R&D group to govern its research activities knowing that any data collected may have to be released without protecting the privacy of subjects. The R&D agency would be ethically obligated to inform the subjects that, although they would make every attempt to protect their confidentiality, since the R&D group is subject to FOIA through its principal funder, the data may have to be released. Knowing that personally identifiable information may have to be released considerably inhibits the nature and quality of research and, in some cases, would preclude the spending of monies in the best manner.

One alternative used by some research institutions concerned about this issue has been the "Canadian Connection." The R&D institution sends their individually identifiable data to Canada where they believe it would not be subject to United States subpoena.

However, the Supreme Court decision issued in the Forsham v. Harris suit greatly enhances the position of R&D educational researchers. In this case, the issue was whether or not the petitioners could require HEW to make raw data available from a study that was funded by the

National Institute of Arthritis, Metabolism and Digestive Diseases (a federal agency). The issue was that under the Freedom of Information Act, federal courts are empowered to order a "agency" to produce "agency records and property withheld" from an individual requesting access. In this case, the agency refused to provide the raw data requested by Peter H. Forsham et al. The court held that HEW need not produce the requested data because they are not "agency records" within the meaning of the FOIA. Data generated by a privately controlled organization which has received federal grants, but which data has not at any time been obtained by the agency, were not held to be "agency records" accessible under FOIA. Two additional court decisions have reaffirmed the Forsham decision regarding which data and reports are accessible to the public. In Kissinger v. Reporters Committee, it was decided that agencies are not required to retrieve documents disposed of prior to the FOIA request. In the second case, Hoover v. U.S. Department of Interior, the ruling was that an evaluation report prepared by a outside consultant can be exempt from FOIA disclosure providing it was not submitted to the funding agency.

Current Operating Procedures

Investigation of current operating procedures within the federal government reveals nine areas which constitute an unintentional and in some cases informal system for the protection of human subjects. These interrelationships continue to be questioned, since Congress and the Department of Education have not sat down and consciously planned an interwoven system. These nine areas include the following:

(1) The Institutional Review Board process for the protection of human subjects as discussed previously in this paper.

(2) Restrictions on data maintained by the federal government and by school districts as provided in the Privacy Act of 1974 and the Family Educational Rights and Privacy Act.

(3) Parental consent for minors completing survey instruments. Although the degree to which this is enforced is unknown, and prior NIE regulations provide for a waiver of parental consent by the director, this is an area requiring attention.

(4) RFP review. Proposal review by peer review committees and Institutional Review Boards provide a trigger for a review of protection mechanisms.

(5) Local superintendent approval. All educational research proposed to be conducted in schools undergoes a comprehensive scrutiny at the local education level.

(6) The Council of Chief State School Officers (CCSSO). Since 1972, a review committee on evaluation and information systems composed of state level representatives has reviewed all major data collection efforts of the federal government.

(7) Federal Education Data Acquisition Council (FEDAC). This Council mandated by Congress in 1978, has developed regulations specifying procedures for federal agencies and contractors who do studies for federal agencies must follow for education

data collection activities. This Council has not met for two years.

(8) Forms clearance process. The Paperwork Reduction Act of 1980 gave the Office of Management and Budget unprecedented authority to monitor and control data collection activities of the Federal Government conducted under contracts. The Division of Education Data Control in the Department of Education administers this Act. Among the requirements is (a) publication of a project summary describing instruments and designs in the Federal Register by February 15 preceding the school year in which the data will be collected and (b) the Annual Information Collection Budget process limiting the number of hours of data collection each agency can require.

(9) The Hatch Amendment[9]. Under this amendment instructional materials used in research must be available for public inspection. Furthermore, no student may be required to participate in projects involving psychological testing or treatment.

Future Considerations

The dilemma continues between self-regulation and federal control in the review of educational research from the privacy and protection of human subjects standpoints. Pressures exist for increased government controls, more detailed code of ethics, and/or more powerful professional review committees. For example, in its advisory report to

the President, the Heritage Foundation[10] has recommended the following:

(1) The Secretary of Education should give priority to enforcing the Hatch Amendment through regulations to implement the law.

(2) Federal regulations should be implemented or new legislation introduced "to affirm the rights of school governing boards, parents, and students" so that "federal grant recipients or contractors provide and publicly announce an opportunity for at least a 30-day public review of all instructional materials, methods and educational programs supported by the federal government. . ."

(3) "A requirement for informed written consent of the parent or legal guardian of a minor student or of an adult student prior to (a) participation or assignment in any innovative, experimental or trial program administered or supported during development or implementation by the Federal Government; and (b) participation or assignment of a pupil in any values clarification exercise, encounter or sensitivity training group or other psycho-social activity in connection with any federally administered or supported activity, project or program."

(4) The Department of Education "should establish a blue-ribbon panel of concerned parent group representatives, constitutional scholars, civil liberties

representatives, and other concerned citizens to draft and recommend a Code of Privacy Standards to govern all education activities, projects and programs administered or supported by the Federal Government, in order to prevent invasion of personal privacy of individual students and their families as a consequence of such activities, projects and programs."

(5) "The administration should enact regulations or recommend legislation based on the proposed Code of Privacy Standards. . ."

(6) "The 'Policy on the Protection of Human Subjects' adopted by DHEW in 1971 should be expanded to include any education activity. project or program administered or supported by the Federal Government, in order to insure that no student or teacher would be placed 'at risk' by being exposed to possible physical, psychological, sociological, or other harm through participation in such activity, project or program."

(7) "The Administration should propose legislation to terminate federal support for development and marketing of school course (curriculum) materials, so that full responsibility and control over this important area would be returned to State and local education agencies and private schools, in conjunction with private sector commercial firms."

If, indeed, President Reagan does decide to accept the recommendations of the Heritage Foundation, I would urge the administration to review the historical and current problems of taking the medical/biomedical research model and applying it to education. We must constantly impress upon Congress and the administration the differences between conducting research in a medical context and an educational context. I believe we were successful in doing this when HHS issued its January regulations.

Furthermore we need to continually push for a code of ethics for educational research. Without a code of ethics, educational R&D professionals do not know what the consensus guidelines are, encouraging confusion about what is ethical behavior in educational R&D context. Ethical issues are broad in perspective relating to every phase of the R&D process--from the issues addressed and how projects are funded through accountability and quality assurance. Each educational R&D person makes his or her judgments about ethical problems in relative isolation without information on how others might resolve similar conflicts. Furthermore, when Congress or commissions examine standards of educational R&D, there is no code of ethics to show our concern. As professionals, we must not wait for a code of ethics to be legislated for us.

APPENDIX

RESEARCH FOR BETTER SCHOOLS CASE STUDY

Introduction

The review procedures used by Research for Better Schools, Inc. (RBS) provide an insightful case study and model for the processes used to protect human subjects. RBS is committed to improve the quality of instruction as it is actually delivered to the student. To accomplish this mission, RBS is involved in developing, evaluating, and disseminating products that will optimize opportunities for intellectual growth as well as promote self-reliance, responsibility and responsiveness to changing social and technological environments; and providing technical assistance to local, intermediate and state educational agencies. For this type of institution, the ethical considerations, some of which are unique to education, are constantly highlighted to assure that the rights and welfare of the subjects involved in research and development activities are adequately protected.

RBS receives the majority of its funding from first the Department of Health, Education and Welfare and now Department of Education through the Office of Education (1966-1972) and the National Institute of Education (1973 -). Therefore, in 1972, RBS prepared its initial policy and procedures, signed a Statement of Compliance for General Institutional Assurance, and submitted them to the Institutional Relations Branch, Division of Research of the National Institutes of Health. This policy and the procedures were revised July 25, 1975 to comply with the Part 46 of Title 45 of the Code of Federal Regulations as amended March 13, 1975. To fulfill its obligation, RBS established a committee competent

to review projects and activities that involve human subjects. In appointing the members of the Committee, the Executive Director stipulated two conditions: (1) members of the RBS staff would be excluded and (2) representatives from different disciplines would be included. Conflict of interest would not be a problem since committee members would be non-RBS staff. Furthermore, a more detailed examination of plans and proposals would occur if outsiders were brought in as consultants for ethical review only.

The second condition, an inter-disciplinary committee in which each member could bring his expertise to the ethical analysis of activities, was met by choosing a lawyer, a school principal, a psychologist, an educational R&D specialist and a member of the RBS Board of Directors to serve on the review committee.

Review of curriculum and evaluation designs and materials is conducted three times a year with objectivity and in a manner to ensure the exercise of independent judgment of the members. Materials to be submitted to the IRB are determined by the principal investigator and a member of the RBS staff who serves as a committee liaison. The information provided to the IRB usually consists of a general description of the project, examples of curriculum materials, plans for collecting and using data, all evaluation instruments, and procedures for protecting confidentiality of subjects. Submitted with the materials is the following form showing the investigator's assessment of the risk involved:

> "I have read the attached instructions concerning human experimentation and herewith submit to the Institutional Review Board all the information it needs to judge the risks within this program.

1. Having read the preceding statement defining risk, in my opinion, the risk for the subjects in the proposed project is:

_____none

_____minimal

_____some

_____acceptable and within expected bounds

_____acceptable but exceeding expected bounds

_____not acceptable

2. I am attaching information which includes:

   a. provisions to be used in guarding the rights and welfare of the human subjects in this research

   b. a description of the methods to be employed for securing Informed Consent of the subjects, where necessary, with copies of the form and explanation to be used

   c. a description of the risks to the subjects and the potential benefits of this research to the subjects and to the public.

Should any change in methods become advisable, I will bring this to the attention of the Institutional Review Board before changes are initiated."

In attendance at the IRB reviews are the five appointed members (three are required for a quorum); an RBS staff member who is the liaison between the RBS investigators, the Committee and DHEW; and the Director of Evaluation. The liaison is responsible for the documentation and minutes of IRB reviews. At its first meeting, the Committee chose not to elect a chairman; instead, all members have equal authority. If a member has a concern, then all members must interact until the question is resolved.

In reviewing projects, the IRB is guided by the Ethical Standards of Psychologists and Ethical Principles in the Conduct of Research with

Human Participants, American Psychological Association. Since educational research has no comparable code of ethics at this time, this one, from the discipline of psychology, is the closest in applicability.

Areas investigated by the Committee include the confidentiality of subjects and the collection, inter-connection and utilization of data in the cognitive and affective areas, both at RBS and on site (the school). The IRB's review of proposals includes questions such as:

- What is the degree of risk?
- Is the risk unusual?
- Is the risk extended?
- How many subjects are at risk?
- Is the risk worth the gain?
- What is the type of risk? one of causing anxiety? invasion of privacy? causing discomfort? threat to dignity or self-image? economic loss?

Guiding Principles

Since the Institutional Review Board was established in 1972, the following guiding principles, both general and specific, have been developed based on the review of Research for Better Schools' proposals and plans. Thus, they represent case law and should not be interpreted as all inclusive.

There are three general principles which have been developed by this Institutional Review Board (IRB):

(1) Fundamentally, the research methods used by RBS should not expose subjects to unnecessary risks. An individual is considered to be at risk if he/she may be exposed to the possibility of injury -- physical, social, emotional or cognitive -- as a consequence of any participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his or her needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. Illustrative of the possible risks involved are the following:

Loss of time	Loss of social acceptance
Anxiety and frustration	Loss of privacy
Public ridicule	Loss of equal opportunity in employment
Harrassment	Denial of knowledge acquisition
Loss of institutional funding	Loss of personal income

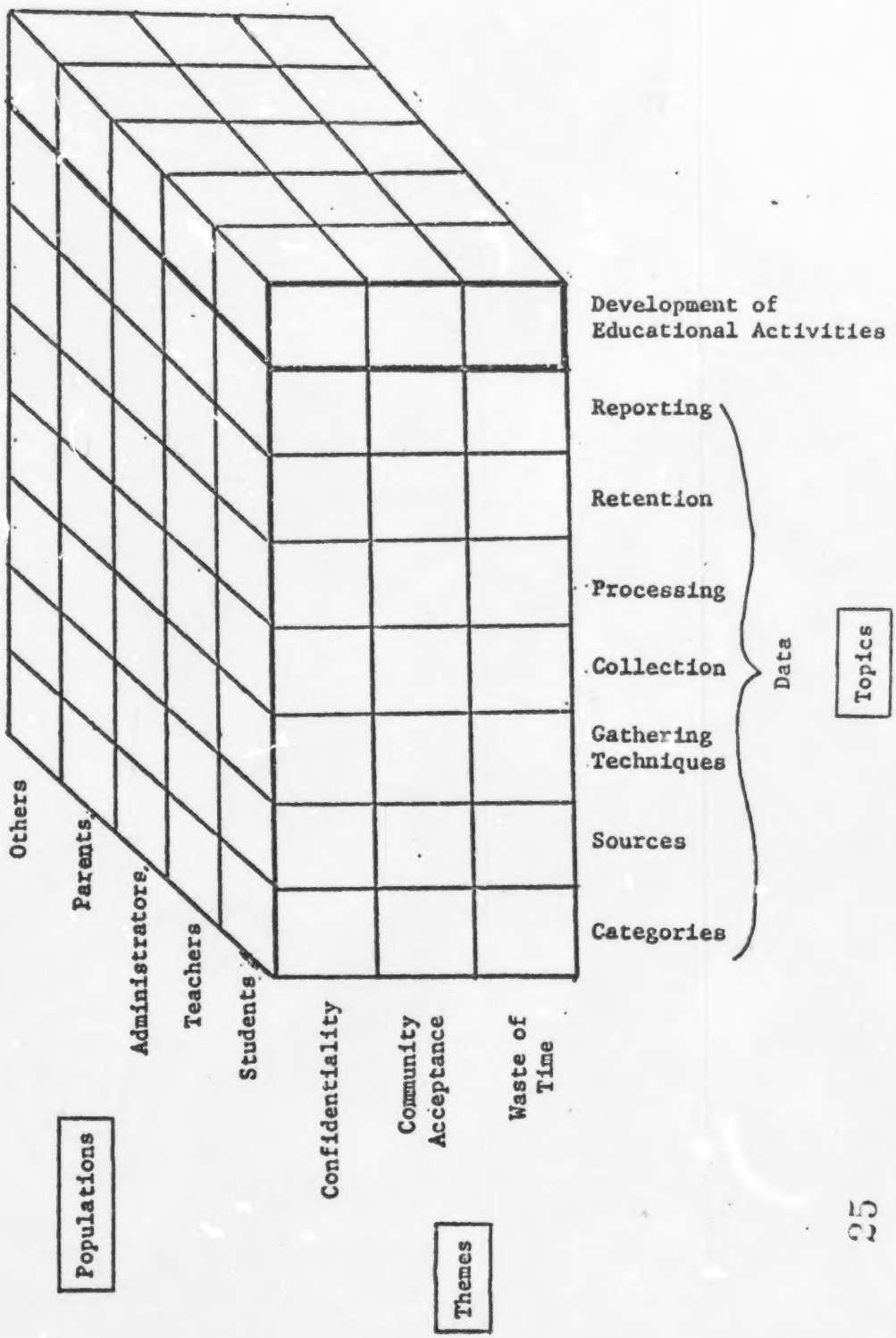
If, in the course of its reviews, the IRB finds a deviation from the above general principle, appropriate changes will be made or requested.

(2) Safeguarding the rights and welfare of subjects at risk in activities supported under grants and contracts from government agencies is primarily the responsibility of the organization which receives or is accountable for the funds involved.

(3) All RBS activities previewed by the IRB will be monitored through an annual review.

An examination of the specific principles which have been developed demonstrates that they compose three interrelated dimensions: topics, populations, and themes. This is displayed on the following page. Following this chart each dimension will be considered separately with an attempt, where possible, to state a generic principle, and then to apply it to the specific subsets.

INTERRELATED DIMENSIONS FOR EXAMINING RISKS



Themes

IRB's principles basically relate to three general themes:

1. Confidentiality of data collected about an individual or institution is one of the primary concerns of the IRB. The identification of subjects, schools and school districts should not be readily reconstructable and should be reconstructable, of course, only by authorized personnel. Furthermore, all reasonable steps are taken to prevent disclosure to unauthorized persons of the responses and/or test results of any individual participant. More specific guidelines related to confidentiality may be found under data collection, processing and retention.

2. Community acceptance, as it applies to instrumentation or the development of educational activities, may be defined as agreement that what is being developed is generally acceptable as a normal part of the educational experience, either instruction or evaluation.

3. Waste of time or economic risk is the third major concern. Whether applied to a participant in an educational activity who may not learn as much as an alternative program, or to an individual responding to a questionnaire in which the items, due to their poor quality, are invalid, the number of subjects involved should be as small as can reasonably be arranged consistent with the objective of the research and development activity. As the risk is reduced, the number of subjects involved can be increased.

Topics

There are two major topics, the first related to data and the second to the development of educational activities.

Data

Data regarding an individual is of concern from the nature of the information collected, to the sources used, through the processing, reporting and retention. More specifically, the following principles have been developed:

(1) Data are collected in the following categories:

Category	Guiding Principles
Directory information, e.g., age, sex, race, school building, class.	Personal demographic information such as religion and ancestry should not be asked.
Socio-economic information, e.g., salary, number of dependents.	
Achievement	
Ability	
Attitudinal	
Work history	
Activities in context, e.g., observational data.	

(2) Sources of data may involve:

Category	Guiding Principles
Individual as subject (e.g., student, teacher, principal, central office staff).	Information that is personally evaluative should not be asked. If the information is not a matter of objective fact but involves a judgment by the respondent, asking the question may be personally damaging. (Example: In one project the procedures used in collecting initial screening data were changed as not to include asking the students to request letters of recommendation.)

Category	Guiding Principles
Subject's parents	Questions should not be asked of parents which appear to suggest that they take certain actions with respect to their children when such actions, if taken, might turn out to be counter-productive to learning. (Example: RBS should not develop questionnaires which imply values, and hence suggest, by implication, action.)

(3) Data Gathering Techniques include, as examples, instrumentation and observations.

Category	Guiding Principles
Instruments	Authority to review standardized cognitive instruments is delegated to the Division Director and the corporation's liaison with the IRB (JoAnn Weinberger). The IRB must review and approve the use of non-standardized cognitive and all effective instruments as follows: - non-standardized, non-cognitive instruments to be administered to over 100 subjects must be previewed. - non-standardized, non-cognitive instruments to be administered to under 100 subjects must be reviewed on a sample basis. - non-standardized. Instruments which have been approved by the IRB for a particular use must receive another review if they are to be distributed or used in a different manner. (Example: Career Education survey instruments were approved for use initially to evaluate RBS model. When marketed, however, additional concerns included potential use and confidentiality of data.)

Category	Guiding Principles
Observation	Unobtrusiveness on the part of the observer is critical.

(4) Data Collection relates to maintaining the confidentiality of data and assurances of confidentiality which can be given to subjects. Regarding the confidentiality of data, the identification of subjects, schools and school districts should not be readily reconstructable and should be reconstructable, of course only by authorized personnel. More specifically, the guidelines to be followed are:

- Whenever it can be accomplished with reasonable economy and convenience, pupil names should be replaced by codes before data enter RBS. Using this procedure no information at RBS could be associated with the individual supplying it and the subjects would be protected.

- Questionnaires being returned to RBS should come from the subject, not from an intermediary in order to protect confidentiality. (Example: A teacher completing a survey should mail to RBS directly and should not be expected to give it to the principal to log-in.)

With regard to assurance of confidentiality, RBS takes all reasonable steps to prevent disclosure to unauthorized persons of the responses and/or test results of any individual participant. Upon request or when otherwise considered desirable, potential or active participants may be given this assurance, but at the same time, they must be informed of the possibility that RBS may be forced to supply confidential data to previously unauthorized personnel through the "right to know" proceedings under the federal Freedom of Information Act.

(5) Data Processing refers to the methods used in handling data to insure confidentiality: coding, storing and computer or hand processing. Particular guidelines which have been developed in this area include:

- Names and coded data should be kept in separate locations. (Example: Class lists and data should be kept in locked file cabinets in separate offices.)

- The computer should not be able to associate pupil names with research data at the computer center. Research data are defined as information not reported by individual names.

RBS staff will use the above criteria for data processing to provide procedural guidance. Only procedures which are different than the standard IRB approved process will be previewed.

(6) Retention of Data refers to the storage of personally identifiable data. In general, personally identifiable data which is collected to evaluate effectiveness of a product is kept until the product has been approved by the Joint Dissemination Review Panel, a publisher/distributor is obtained, five years have transpired and/or the data is no longer needed for legitimate research. Retention for longer periods may be permitted on approval by the Executive Director where certain irreplaceable data is highly valuable as support for RBS research or as an aid to the future generation of important hypotheses.

(7) Reporting relates to the preparation of reports and the uses of the data. Relating to confidentiality is the need in the preparation and distribution of reports to prevent identification or linkage of data supplied by or descriptive of any one person or organization. This is most difficult when utilizing case studies. Thus, the recorder must take special care to disguise as much as possible without degrading important research information the identities involved. Special attention must be paid to the following:

- If a statement is not pertinent or acceptable as proof, do not report it.
- Clearly label observations separately from recommendations.
- Avoid inflammatory remarks.
- Restrict distribution of possible "high risks" reports to "right-to-know" persons.
- Submit all case studies to IRB for review.

Other issues related to reporting involve potential risks to teachers and to students. With regard to teachers, question of risk is when the responses of students about the instructional process are given to the school principal or to the district superintendent. The criteria for considering the extent of risk in this situation are:

- It is generally acceptable procedure for responses to such items to be presented to principals and other administrators.
- The teacher has seen the instrument before administering it and has not objected to its use.
- Benefits to the students outweigh the risks to the teacher as an object of investigation.

- The RBS staff will help administrators interpret the data since the teacher is one element in the instructional process but other elements can also affect student learning and attitude.

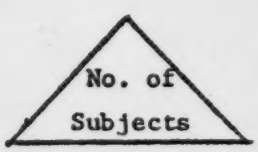
Risks to students may result if data are given to a school to augment the permanent record of a student unless the data have been collected by RBS for its research and the school would otherwise have collected the same data. The IRB should be kept informed about any information being returned to schools about individual students. (Example: In one project, the information being returned to the student's home school, standardized achievement test scores, was reviewed and approved since the pupil record was not being augmented by information the school district did not usually collect. In another project, identifiable student data were returned to the school because the instruments and scoring service were purchased by the school district.)

RBS should not be held responsible for arrangements adopted by a school to use intelligence and standardized achievement test data that RBS supplies to the school in lieu of data from the regular school district testing program. To reduce the risk that a school will misuse research or development data supplied to it by RBS the school should be required to seek permission of RBS before releasing data which RBS has supplied.

Development of Educational Activities includes issues related to community acceptance, length of treatment, affective curriculum, and informed consent.

One criterion for determining the acceptability of a purpose or procedures is acceptance on the part of the community as a normal part of an educational treatment.

The number of subjects involved should be as small as can reasonably be arranged consistent with the objectives of the research and development activity. As the risk is reduced, the number of subjects involved can be increased. This developmental cycle may be represented as follows:



Try-out

Pilot Test

Field Test

Economic risk as applied to a participant in an educational program is most likely to be a waste of time. However, in this development cycle the attendant risks are considered minimal since the subject could recover in a reasonable amount of time.

To reduce economic risk, the developmental cycle should provide for short unit sequences tested and then modified, with the sequences being as short as feasible to minimize possible time loss for students. (Example: Developmental cycles for individualized products were examined for compliance. Possible risks in these areas were: (a) a pupil would waste time in school, and (b) the pupil would not learn the particular subject matter.)

Affective programs designed to influence feelings should:

- Guide subjects in how to recognize their own feelings and those of others.
- Promote understanding of and insight into the sources and causes of feelings.
- Encourage the expression of feelings of socially acceptable ways.
- Focus attention on the specific behaviors of subjects and others which arouse feelings, rather than on their personal characteristics.
- Allow rejection of subjects' specific behaviors while avoiding rejection of subjects themselves.
- Emphasize changing behaviors as a way of changing feelings.
- Provide teacher training so that teachers can identify and handle problem situations such as subjects' feelings of rejection.
- Arrange for the signing of "Informed Consent" forms which comply with DHEW requirements.

RBS should inform and obtain a written consent on the use of any curriculum and/or teaching procedure in any formalized program which poses unusually and extended risk to the individual or which provides materials intended for purposes other than program evaluation and revision.

7/11/78

FOOTNOTES

[1] Family Educational Rights and Privacy Act, P.L. 93-380, 88 Stat. 484 (1974), codified at 5 U.S.C. § 552.

[2] Freedom of Information Act, P.L. 90-23, 81 Stat. 54 (1967) as amended by P.L. 93-502, 88 Stat. 1561 (1974), codified at 5 U.S.C. § 552.

[3] Privacy Act of 1974, P.L. 93-579, 88 Stat. 1896 (1974), codified at 5 U.S.C. § 552.

[4] National Research Act of 1974, P.L. 93-348, 88 Stat. 342 (1974).

[5] U.S. Privacy Protection Study Commission, Personal Privacy in an Information Society, The Report of the . . . Commission, Washington, D.C.: Government Printing Office, 1977.

[6] Institutional Guide to DHEW Policy on Human Subjects, DHEW (NIH) Publication #72-102 (1971).

[7] Protection of Human Subjects, 45 CFR, Part 46.

[8] Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects, 45 CFR, Part 46 as published in the Federal Register, Vol. 46, No. 16.

[9] Hatch Amendment, P.L. 95-561, 92 Stat. 2355 (1978), codified at 20 U.S.C. 1232h.

[10] The Heritage Foundation, Mandate for Leadership, Project Team Report for the Department of Education, 1980.

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General Education Provisions Act, P.L. 90-247 § 400, 81 Stat. 814 (1968) as amended, (codified at 20 U.S.C. § 1221)

National Research Act of 1974, P.L. 93-348, 88 Stat. 342 (1974), (codified in scattered sections of 42 U.S.C.)

Paperwork Reduction Act of 1980, P.L. 96-511

Privacy Act of 1974, P.L. 93-579, 88 Stat. 1896 (1974), (codified at 5 U.S.C. § 552a)

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34 CFR 5b Privacy Act Regulations, 45 Federal Register 30808, May 9, 1980.

34 CFR 5, Freedom of Information Act Regulations, 45 Federal Register 30803, May 9, 1980.

41 CFR 34, Education Department Procurement Regulations, 45 Federal Register 49032, July 22, 1980.

45 CFR 46 et. seq. Protection of Human Research Subjects

34 CFR 99 Privacy Rights of Parents and Students, 45 Federal Register 30911, May 9, 1980.

45 CFR 1400 National Institute of Education

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43 Federal Register 31786 (1978) to be codified at 45 CFR 46 Regulations to establish HEW policy on Research Involving Children

44 Federal Register 2084 (1978) to be codified at 45 CFR 46. Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

44 Federal Register 46535 (1979) (Federal Education Data Acquisition Council Guidelines)

44 Federal Register 47687 (1979) to be codified at 45 CFR 46 Regulations amending HEW policy on Protection of Human Research Subjects

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